

3/24/99

K984062

## 8.0 510(k) Summary

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### 510(k) Summary (As required by 21 CFR 807.92)

#### A. Submitter Information

Submitter's Name: Daig Corporation, a St. Jude Medical Company  
Address: 14901 DeVeau Place  
Minnetonka, Minnesota 55345-2126 U.S.A.  
Telephone Number: (612) 933-4700  
Contact Person: Todd J. Kornmann  
Date Submission Prepared: November 13, 1998

#### B. Device Information

Common or Usual Name: Seal-Away™ Hemostasis Adapter  
Classification Name: Introducer  
Predicate Device: Removable Hemostasis Adapter with Sideport (K894343)  
Device Description: The Daig Seal-Away™ Hemostasis Adapter is an Introducer Accessory designed to provide easy access to the vascular system while providing convenient temporary closure of a standard indwelling introducer access site during introduction of pacing leads, angiographic catheters, closed end catheters, balloon catheters and electrodes into a vessel.  
Intended Use: The Daig Seal-Away™ Hemostasis Adapter is designed to minimize the blood loss during the introduction of angiographic catheters, closed end catheters, balloon catheters and electrodes into a vessel. (same as predicate device)

#### C. Comparison of Required Technological Characteristics

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All technological characteristics of the Seal-Away™ Hemostasis Adapter are substantially equivalent to the predicate device (K894343) including product design, packaging, sterilization, and labeling.

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### **D. Support of the Substantial Equivalence**

Daig Corporation considers the Seal-Away™ Hemostasis Adapter to be substantially equivalent to the following predicate device: the Removable Hemostasis Adapter with Sideport used with the Percutaneous Catheter Introducer which received marketing clearance on September 26, 1989 (K894343).



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAR 24 1999

Mr. Todd Kornmann  
Senior Regulatory Affairs Specialist  
DAIG Corporation  
14901 DeVeau Place  
Minnetonka, MN 55345-2126

Re: K984062  
Trade Name: Seal-Away™ Hemostasis Adapter  
Regulatory Class: II  
Product Code: DYB  
Dated: February 18, 1999  
Received: February 19, 1999

Dear Mr. Kornmann:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

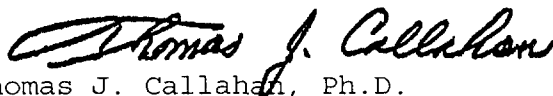
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any

obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



Thomas J. Callahan, Ph.D.

Director

Division of Cardiovascular, Respiratory  
And Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

510(k) Number (if known): K984062

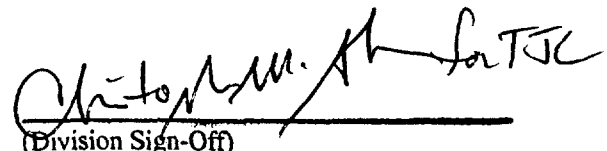
Device Name: Seal-Away™ Hemostasis Adapter

Indications for Use:

The Seal-Away™ Hemostasis Adapters are designed for the introduction of angiographic catheters, closed end catheters, balloon catheters and electrodes into a vessel where minimizing the blood loss is essential.


(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
(Division Sign-Off)

Division of Cardiovascular, Respiratory,  
and Neurological Devices

510(k) Number \_\_\_\_\_  
OR Over-The-Counter Use \_\_\_\_\_  
(Optional Format 1-2-96)

Prescription Use   
(Per 21 CFR 801.109) \_\_\_\_\_